HFI -35

DEPARTMENT OF HEALTH & HUMAN SERVICES

John E Klemes C.O. 10/15/99 M3 0d n

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
2000-DT-02

October 14, 1999

Mr. Andrew J. Reid
Executive Director
Jones Clinic Physician Network, L.L.C.
110 Ridge Road
Munster, IN 46321

Dear Mr. Reid:

We are writing you because on October 5, 1999, your facility was inspected by a representative of the State of Indiana, acting in behalf of the Food & Drug Administration (FDA). The inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed the following level 1 findings at your facility:

1. Weekly phantom images were not done during the time period of June 9, 1999 to September 30, 1999. This represents a total of 12 weeks that were missed. These absent phantom images applied to the [redacted] mammography system that was replaced by a [redacted] mammography machine put in service on October 1, 1999.

2. Your patient notification of mammography results is inadequate in that a) there is no system in place to provide timely reports to patients and b) there is no system in place to communicate serious or highly suggestive cases of malignancy as soon as possible.

The specific problems noted above appeared on your MQSA Facility Inspection Report (copy enclosed), which was issued at the close of the inspection. These problems are identified as level 1 because they identify a failure to meet a significant MQSA requirement.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a violation of law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. These level 2 findings are:

1. There was no written procedure available for handling consumer complaints at your facility.

2. There were no written procedures available for infection control practices at your facility.

3. There was no record of corrective action, prior to any further exams, for a failing phantom image score on the [redacted] system.

4. A random review of medical reports revealed that 3 of 5 reports did not contain an assessment category as required by the Standard.

5. There were no examples or attempts to obtain biopsy results in order that outcome audit may be correlated for your facility as a whole and also by the individual interpreting physician.

6. There was no designation of a Lead Interpreting Physician responsible for the quality assurance program of your facility.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct the Level 1 and 2 violations noted in this letter;

- each step your facility is taking to prevent the recurrence of similar violations;

- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and

- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records. (Note: Patient names or identification should be deleted from any copies submitted.)

Please submit your response to: Mr. David M. Kaszubski
Director Compliance Branch
U.S. Food & Drug Administration
1560 East Jefferson Ave.
Detroit, MI 48207

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective actions, you should consider the more stringent State requirements, if any. You should also send a copy to the State of Indiana radiation control office that conducted the inspection referenced in this letter. You may choose to address both the FDA and any additional State requirements in your response.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter only pertains to findings of your inspection and does not necessarily address other obligations you have under law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. Dennis E. Swartz, Radiological Health Expert, at 313-226-6260 Ext. 155.

Sincerely yours,

John P. Kempster for

Raymond V. Mlecko
District Director
Detroit District

Enclosures:a/s